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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
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EXAMINER	
WELTER, RACHAEL E	
ART UNIT	PAPER NUMBER
1611	
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Please find below and/or attached an Office communication concerning this application or proceeding.

The time period for reply, if any, is set in the attached communication.

Office Action Summary	Application No.	Applicant(s)	
	10/530,326	HASENZAHL ET AL.	
	Examiner	Art Unit	
	RACHAEL E. WELTER	1611	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE *3* MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☒ Responsive to communication(s) filed on *16 July 2010*.

2a)☐ This action is **FINAL**. 2b)☒ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) *1-3* is/are pending in the application.

4a) Of the above claim(s) _____ is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☒ Claim(s) *1-3* is/are rejected.

7)☐ Claim(s) _____ is/are objected to.

8)☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

9)☐ The specification is objected to by the Examiner.

10)☐ The drawing(s) filed on _____ is/are: a)☐ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).

11)☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

12)☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☐ All b)☐ Some * c)☐ None of:

1.☐ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____.

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

1) ☐ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☐ Information Disclosure Statement(s) (PTO/SB/08) Paper No(s)/Mail Date _____.
4) ☐ Interview Summary (PTO-413) Paper No(s)/Mail Date. _____ .
5) ☐ Notice of Informal Patent Application
6) ☐ Other: _____.

DETAILED ACTION

Continued Examination Under 37 CFR 1.114

A request for continued examination under 37 CFR 1.114, including the fee set forth in 37 CFR 1.17(e), was filed in this application after final rejection. Since this application is eligible for continued examination under 37 CFR 1.114, and the fee set forth in 37 CFR 1.17(e) has been timely paid, the finality of the previous Office action has been withdrawn pursuant to 37 CFR 1.114. Applicant's submission filed on 7/16/10 has been entered.

Claim Status

Claims 1-3 are pending. Claims 4-5 are cancelled.

Specification

The objection to the specification is withdrawn in light of applicant's amendments.

Claim Rejections - 35 USC § 102

The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

> A person shall be entitled to a patent unless –
>
> (b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

The rejection of claims 1-2 rejected under 35 U.S.C. 102(b) as being anticipated by Shimizu et al (US Publication No. 2002/0102369) as evidenced by Scholz et al (US Patent No. 6,951,642) is maintained.

Shimizu et al teach a cellulose ester dope composition comprising Aerosil R 972V and benzoin (see paragraph 0272); example 21). As evidenced by Scholz et al, benzoin is a polymerization initiator used in moisturizing skin treatment compositions that aids in the copolymerization of (meth) acrylate and various comonomers (column 9, lines 53-61). Furthermore, as evidenced by the instant specification, Aerosil R 972V is a hydrophobic highly disperse silicon dioxide type that is particularly suitable for the composition (pg. 11, lines 19-27). According to the instant specification, Aerosil R 972V exhibits the instant tamped density, water-wettable contents, and BET surface area (see Table 6, pg. 24).

Response to Arguments

Applicant's arguments filed 7/16/10 have been fully considered but they are not persuasive.

Applicant argues that a reference must teach each and every element required by the claims. Applicant argues that claim 1 is clearly directed to a “solid or semi-solid” pharmaceutical or cosmetic formulation. Applicant submits that the claimed subject matter is clearly not a cellulose ester film for use as a protective film for a polarizing plate as taught in Shimizu.

In response to applicant's arguments and amendments, it is first noted that applicant has not defined such an "active pharmaceutical or cosmetic compound" nor an "effective amount" in the specification. The rejection above provides evidence (Scholz et al) that benzoin is a pharmaceutical or cosmetic compound. To overcome the rejection and distinguish the instant composition from Shimizu, applicant should specify a particular pharmaceutical/cosmetic compound or group of pharmaceutical/cosmetic compounds in the instant claims. Second "a solid or semi-solid" formulation does nothing to distinguish the instant claims from Shimizu. Shimizu is directed to a film which is clearly a solid or semi-solid. Although applicant may not intend for its composition to be a cellulose ester film, the broadness of the instant claims allows them to be anticipated by the composition of Shimizu.

As such, the anticipation rejection over Shimizu is maintained for the reasons stated above.

Claim Rejections - 35 USC § 103

The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

> (a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negatived by the manner in which the invention was made.

The factual inquiries set forth in *Graham* **v.** *John Deere Co.*, 383 U.S. 1, 148 USPQ 459 (1966), that are applied for establishing a background for determining obviousness under 35 U.S.C. 103(a) are summarized as follows:

1. Determining the scope and contents of the prior art.
2. Ascertaining the differences between the prior art and the claims at issue.
3. Resolving the level of ordinary skill in the pertinent art.
4. Considering objective evidence present in the application indicating obviousness or nonobviousness.

This application currently names joint inventors. In considering patentability of the claims under 35 U.S.C. 103(a), the examiner presumes that the subject matter of the various claims was commonly owned at the time any inventions covered therein were made absent any evidence to the contrary. Applicant is advised of the obligation under 37 CFR 1.56 to point out the inventor and invention dates of each claim that was not commonly owned at the time a later invention was made in order for the examiner to consider the applicability of 35 U.S.C. 103(c) and potential 35 U.S.C. 102(e), (f) or (g) prior art under 35 U.S.C. 103(a).

The rejection of claim 3 rejected under 35 U.S.C. 103(a) as being unpatentable over Shimizu et al (US Publication No. 2002/0102369) as evidenced by Scholz et al (US Patent No. 6,951,642) is maintained.

The disclosure of Shimizu et al is discussed above.

Shimizu et al do not teach an amount of Aerosil R 972V that is from 0.01 to 30 wt.% but rather teach an amount that overlaps with the instant amount. Shimizu et al teach that the silicon dioxide particles can be present in an amount of 0.005-0.3 wt.% (column 33, lines 45-48).

However, it would have been obvious to an artisan of ordinary skill at the time the invention was made to modify and optimize the amount of Aerosil R 972V in the composition of Shimizu et al. Optimization of parameters is a routine practice that

would be obvious to a person of ordinary skill in the art to employ and reasonably expect success. One would have been motivated to determine the optimal amount of each ingredient in order to best achieve the desired results, which ultimately depends on the desired matting effect and transparency. See *In re Aller, 220 F.2d 454, 456, 105 USPQ 233, 235 (CCPA 1955)* & MPEP 2144.05.

Response to Arguments

Applicant's arguments filed 7/16/10 have been fully considered but they are not persuasive.

Applicant reiterates that Shimizu is not directed to a solid or semi-solid pharmaceutical or cosmetic formulation and notes that there are no pharmaceutically or cosmetically active compounds present in effective amounts. Applicant submits that the silica employed by Shimizu is a filler and does not aid to facilitate flowability. Applicant does not see why the composition of Scholz is combined with Shimizu. Neither Scholz nor Shimizu desires a flowable powder suitable for tableting or placement in a capsule. Furthermore, applicant does not see how optimization of Shimizu leads to the claimed range.

In response to applicant's arguments, it is noted that the examiner addressed applicant's arguments regarding Shimizu above, which are incorporated herein. Additionally, applicant's argument that the silica is employed for a different purpose than the prior art is not persuasive. It is noted that the instant claims are directed to a composition and as long as the prior art suggests and/or anticipates all the components

of the compositions (Aerosil R972 V), the components are capable of performing an intended function. Applicant also has done nothing to structurally distinguish the instant silica's function and has failed to claim a tablet or capsule. Regarding applicant's argument over Scholz, it is noted that Scholz is only combined with Shimizu to provide evidence that benzoin is a pharmaceutical or cosmetic compound. Furthermore, since Shimizu teaches Aerosil R972 V in an amount of 0.005-0.3 wt.% that overlaps with the instant amount, it would have been obvious to use an amount within the instant range (0.01-30 wt.%) as part of routine optimization. One would have been motivated to optimize the amount of silica in Shimizu depending on the desired matting effect and transparency. Methods of determining appropriate component percentages are well-known in the art, and one of ordinary skill in the art would have arrived at the appropriate percentages via routine experimentation. Manipulation of relative amounts of formulation components do not support the patentability of subject matter encompassed by the prior art, unless there is evidence indicating unexpected results.

As such, it is the position of the examiner that instant claim 3 is rendered obvious over Shimizu as evidenced by Scholz for the reasons stated above.

The rejection of claims 1-3 rejected under 35 U.S.C. 103(a) as being unpatentable over Sebillotte-Arnaud et al (US Publication No. 2002/0039976) is maintained.

Sebillotte-Arnaud et al teach a cleansing composition comprising at least one foaming surfactant, at least one hydrophobic silica, and at least one oxyalkylenated

compound in a physiologically acceptable aqueous medium (paragraph 0011). According to Sebillotte-Arnaud et al, the hydrophobic silica have a specific surface area ranging from 50-500 m^2/g and a compacted density preferably from 50-150 g/L (paragraph 0021; Table 1). Sebillotte-Arnaud et al further teach that the hydrophobic silica can be an amount from 1-15 wt.% (paragraph 0018). Additionally, Sebillotte-Arnaud et al suggest that Aerosil R 972 can be used in the composition.

Although Sebillotte-Arnaud et al teach that the composition can comprise Aerosil R 972, Sebillotte-Arnaud et al do not teach a composition comprising Aerosil R 972V, which meets the instant density requirements. It is noted from the instant specification that a difference between Aerosil R 972V and Aerosil R 972 is the density (see Table 6, pg. 24).

However, it would have been obvious to an artisan of ordinary skill at the time the invention was made to use a hydrophobic silica, such as Aerosil R 972V in the composition of Sebillotte-Arnaud et al. One would have been motivated to do so depending on the silica's desired compacted density and because Sebillotte-Arnaud et al suggest that its silica can have a compacted density in a range from 50-150 g/L, which overlaps with the instant range.

Regarding the limitation, "wherein the silicon dioxide contains a maximum of 3.0 wt.% water-wettable contents," the examiner notes that Sebillotte-Arnaud et al teach hydrophobic silica. Furthermore, the instant specification provides evidence that Aerosil 972 exhibits water-wettable contents of 3 wt.% (see pg. 24, Table 6).

Response to Arguments

Applicant's arguments filed 7/16/10 have been fully considered but they are not persuasive.

Applicant argues that none of the products taught by Sebillotte-Arnaud exhibit the instant tamped density range and are identified as Aerosil R972 V. Applicant notes that there is no mention of tablet or capsules, flowability of granular materials or hardness of tablets in Sebillotte-Arnaud. Additionally, applicant argues that the rejection above does not include a reference showing the existence of AEROSIL R972 V and that it is not clear that a more dense, low structured silica would be suited for use in Sebillotte-Arnaud.

In response to applicant's arguments, it is noted that the prior art does not exemplify an AEROSIL product with the claimed density range, however; Sebillotte-Arnaud suggests a range of density (50-150g/L) that overlaps with the claimed density of 90-400g/L. Clearly, higher more dense, low structured silica are envisioned by the teachings of Sebillotte-Arnaud. The specification was only used to gain a better understanding of the invention and to determine the differences between AEROSIL R972V and AEROSIL R972. In this case, it is clear from the specification and applicant's arguments that a difference between the AEROSIL products is density. The specification was not relied on for any specific teachings and all the limitations of the instant claims are suggested in the teachings of Sebillotte-Arnaud. Furthermore, in regard to applicant's argument that there is no mention of tablets, capsules, etc in Sebillotte-Arnaud, it is noted that the instant claims are not drawn to specific oral

dosage forms, such as tablets, capsules, etc. Thus, it is noted that the features upon which applicant relies (i.e., tablets, capsules, etc) are not recited in the rejected claim(s). Although the claims are interpreted in light of the specification, limitations from the specification are not read into the claims. See *In re Van Geuns*, 988 F.2d 1181, 26 USPQ2d 1057 (Fed. Cir. 1993).

Applicant further argues that the use of different AEROSIL products (AEROSIL R972 V vs. AEROSIL R972) result in different outcomes. Applicant argues that these outcomes would not be expected from the art of record. Applicant directs the examiner's attention to tables 7 and 8 and argues that CP1 and CP2 establish the significance for water-wettable contents making up a maximum of 3.0 wt.% limitation and also density.

Applicant's alleged unexpected results are acknowledged. However, it is the examiner's position that a prima facie case of obviousness has been established. Since Sebillotte-Arnaud teaches a cosmetic formulation comprising AEROSIL R972, which has a water-wettable contents of 3 wt.% and suggests silica with a density of 50-150 g/L, the different outcomes, such as tablet hardness and disintegration time in Tables 7-8 would be intrinsic. Mere recognition of latent properties in the prior art does not render nonobvious an otherwise known invention. *In re Wiseman*, 596 F.2d 1019, 201 USPQ 658 (CCPA 1979).

Furthermore, even if applicant is arguing that the outcomes of the AEROSIL products would be unexpected, these outcomes are not commensurate in scope with the instant claims. According to MPEP 716.02, whether the unexpected results are the

result of unexpectedly improved results or a property not taught by the prior art, the "objective evidence of nonobviousness must be commensurate in scope with the claims which the evidence is offered to support." It is noted that Tables 7 and 8 in the specification, which show the different properties of the AEROSIL products, are all drawn to properties of tablets. However, applicant is not claiming a tablet or solid formulation but rather just a solid or semi-solid composition. Thus, in order to be commensurate in scope with the instant claims, applicant needs to narrow the scope of the instant claims and limit the formulations to a tablet.

As such, it is the examiner's position that the rejection should be maintained for the reasons stated above.

Conclusion

Claims 1-3 are rejected. No claims are allowed.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to RACHAEL E. WELTER whose telephone number is (571) 270-5237. The examiner can normally be reached 7:30-5:00 Monday-Friday.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Sharmila Landau can be reached at 571-272-0614. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see http://pair-direct.uspto.gov. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

REW

/David J Blanchard/
Primary Examiner, Art Unit 1643